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| 09/744,527      | 05/09/2001  | Lydie Bougucleret    | 45.US2.PCT          | 8473             |

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EXAMINER

PAK, YONG D

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 03/22/2006

Please find below, and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/744,527

Applicant(s)

BOUGUELERET, LYDIE

Examiner

Yong D. Pak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 128-137 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 128-137 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application is a 371 of PCT/IB99/01353.

The amendment filed on November 29, 2005, canceling claims 82-127 and adding claims 128-137, has been entered.

Claims 128-137 are pending and are under consideration.

### ***Response to Arguments***

Applicant's amendment and arguments filed on November 29, 2005, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 128-130 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 128-130 are drawn to a polypeptide consisting or comprising an amino acid sequence beginning at the amino acid at position 200 and ending at the amino acid

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in position 300 of SEQ ID NO:4. Therefore, the claims are drawn to a genus of polypeptides having any function. There is no disclosure of any particular structure to function/activity relationship in the disclosed species.

Therefore, many functionally unrelated polypeptides are encompassed within the scope of these claims, including partial amino acid sequences. The genus of these polypeptides comprise a large variable genus with the potentiality of encompassing many different proteins having different activity or no activity. The specification only describes fragments SEQ ID NO:4 having GGPPS activity. The specification fails to describe additional representative species of the polypeptides by any identifying characteristics or properties of the polypeptides other than the structural characteristics recited in the claims, for which no predictability of function is apparent. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 128-130.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

In response to the previous Office Action, applicants have traversed the above rejection. Applicants should note that the rejection has been amended in light of the amendment of the claims.

Applicants argue that there is adequate written description because claims 82-123 have now been canceled. However, newly added claims 128-130 are drawn to polypeptides having any function or no function at all.

Hence the rejection is maintained.

Claims 128-130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide of SEQ ID NO:4 and fragments thereof having GGPPS activity, does not reasonably provide enablement for polypeptides consisting or comprising of amino acids 200-300 of SEQ ID NO:4, wherein said polypeptides have no specific function or any function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

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Claims 128-130 are drawn to a polypeptide consisting or comprising an amino acid sequence beginning at the amino acid at position 200 and ending at the amino acid in position 300 of SEQ ID NO:4 without any function assigned. Therefore, the claims are drawn to polypeptides having any function or no function at all. Therefore, many functionally unrelated polypeptides are encompassed within the scope of these claims, including variants, mutants, recombinants and partial amino acid sequences. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The claims broadly encompass variants, mutants and recombinants having any or no activity at all. Therefore, the breadth of these claims is much larger than the scope enabled by the specification. The function of a polypeptide cannot be predicted from its structure and the specification does not teach how to use polypeptides having any function or having no activity. The quantity of experimentation in this area is extremely large since there is significant variability in the activity of the polypeptides in the claims. It would require significant study to identify the actual function of the polypeptides and identifying a use for the claimed polypeptides would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its activity. Even very similar proteins may have every different functions. In the current case, where no specific information is known

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regarding the function, it is entirely unpredictable what function and activity will be found for the protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the encoded polypeptides.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polypeptides comprising or consisting of amino acids 200-300 of SEQ ID NO:4, wherein said polypeptides have any function or no function at all. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of said fragments of SEQ ID NO:4 having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office Action, applicants have traversed the above rejection. Applicants should note that the rejection has been amended in light of the amendment of the claims.

Applicants argue that that the claims are fully enabled by the specification because claims 82-123 have now been canceled. However, newly added claims 128-130 are drawn to polypeptides having any function or no function at all.

***Claim Rejections - 35 USC § 102/103***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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Claims 128-137 are rejected under 35 U.S.C. 102(e) as being anticipated by Greene et al.

Claims 128-137 are drawn to a polypeptide comprising or consisting of SEQ ID NO:4 and a polypeptide comprising or consisting of amino acids 200-300 of SEQ ID NO:4, wherein said polypeptide has geranylgeranyl pyrophosphate synthetase (GGPS) activity.

Greene et al. (US Patent No. 5,786,193— form PTO-1449) discloses a polypeptide that is 100% identical to SEQ ID NO:4 of the instant invention, wherein said polypeptide has (GGPS) activity (US Patent No. 5,786,193 – Figure 3). Therefore, the polypeptide of Green et al. comprises amino acids 200-300 of SEQ ID NO:4 and comprises or consists of SEQ ID NO:4. Although fragments consisting of 200-300 of SEQ ID NO:4 are not explicitly disclosed in Greene et al., Greene et al. discloses enzymatically active fragments of GGPPS (Columns 3-4). Therefore, the reference of Greene et al. anticipates claims 128-137.

Claims 128-137 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Greene et al. and/or Ping-Fan.

Claims 128-137 are drawn to a polypeptide consisting or comprising of SEQ ID NO:4 and comprising or consisting of amino acids 200-300 of SEQ ID NO:4, wherein the polypeptide has GGPPS activity.

Green et al. discloses a human GGPPS that is 100% identical to SEQ ID NO:4 of the instant invention, as discussed above. Therefore, the polypeptide of Green et al.

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comprises amino acids 200-300 of SEQ ID NO:4 and comprises or consists of SEQ ID NO:4. Although fragments consisting of 200-300 of SEQ ID NO:4 are not explicitly disclosed in Greene et al., Greene et al. discloses enzymatically active fragments of GGPPS (WO 96/21736 – pages 6-8). Therefore, the reference of Greene et al. anticipates claims 128-137.

Alternatively, it would have been obvious to one having ordinary skill in the art to make enzymatically active fragments of SEQ ID NO:4.

Ping-Fan (US Patent No. 5,849,882 – cited previously on form PTO-892) discloses making enzymatically active fragments of a protein by hydrolysis of the protein (Column 3 and 5-6).

Therefore, combining the teachings of the above references, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make fragments of SEQ ID NO:4 having GGPPS activity using the polypeptide taught by Greene et al. and using Ping-Fan. One of ordinary skill in the art would have been motivated to make such enzymatically active fragments of GGPPS of Greene et al. in order to reduce the size of the enzyme. One of ordinary skill in the art would have had a reasonable expectation of success in making said fragments consisting of fragments of the GGPPS of Greene et al. since Ping-Fan teaches how to make enzymatically active fragments of a protein of interest.

Therefore, Greene et al. and Ping-Fan. render claims 130 and 135 *prima facie* obvious to those skilled in the art.

None of the claims are allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

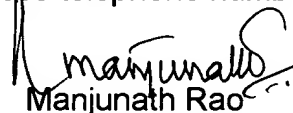
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak  
Patent Examiner 1652

  
Manjunath Rao  
Primary Patent Examiner 1652